REMARKS

This Amendment is filed in response to the Final Office Action dated February 25, 2003 wherein claims 1-36 stand rejected under 35 USC 102.

Claim Rejections - 35 USC §102

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Claims 1-36 are rejected under 35 U.S.C. 102(b) as being anticipated by Meyer et al. (U.S. Pat. No. 5,958,902).

Meyer teaches the application of a lung surfactant to the posterior pharyngeal region prior to sleep to reduce episodes of sleep disturbance resulting in apnea. The lung surfactant is provided in a convenient applicator container and can be any commercially available surfactant such as Exosurf®. Exosurf contains phospholipids and tyloxapol. Meyer teaches that U.S. Pat. No. 4,826,821, incorporated by reference, teaches using synthetic surfactant compositions containing tyloxapol. U.S. Pat. No. 4,826,421 teaches that surface-active agents such as tyloxapol can be present in the compositions from 6-11%. Meyer further teaches that the pharmacologically effective dose can range from 0.25 to 2.75 mg in 0.75 to 1.25 ml.

During application of the invention of Meyer, a pressurized aerosol can, a squeeze bottle or a pump bottle may be used. The surfactant will typically be applied through the oral cavity, but it may be delivered nasally when the subject is supine.

Applicants disagree with Examiner's interpretation of the previously used phrase "consisting essentially of" as meaning "comprising". Examiner is also misinterpreting the prior art in that, for example, Examiner quotes Mayer as teaching that the pharmacologically effective dose can range from 0.25 to 2.75 mg in 0.75 to 1.25 mg. It is true that Mayer have disclosed this range

but his disclosure pertained to range of the pulmonary alveolar surfactant EXOSURF and not to the range of tyloxapol or any other alkylaryl alcohol polymer. The range is applicable to surfactant disclosed by Mayer as a whole including phospholipids and tyloxapol but has no bearing on the present amounts of the tyloxapol according to the current invention. The same is valid for the '821 patent, wherein the 6-11% of tyloxapol cited is the 6-11% of the synthetic surfactants the '821 is disclosing.

However, to expedite the prosecution of this application and to bring it to issue, Applicants amended claims to read only as "consisting of the alkylaryl polyether alcohol polymer alone or in admixture with a pharmaceutically acceptable excipient, additive or diluent". Excipients, additives or diluents are supported in the Composition and Formulation sections of the Specification on pages 21-27 and 31-33. This amendment clearly removes the claims from any possibility of being anticipated by the cited prior art. By limiting the claims to a phrase "consisting of" the only possibility for the claim to consist of is one or several alkylaryl polyether alcohol polymers alone or in combination with an excipient, additive and/or diluent. Neither of the cited prior art utilizes any of the alkylaryl polyether alcohol polymers alone or in combination with pharmacologically inactive excipient, additive or diluent.

Examiner further argues, in response to Applicants prior arguments, that in the instant specification, it is not clear what are the basic and novel characteristics of tyloxapol. Thus, one cannot differentiate between the instant invention and the product Exosurf® as used in the prior art.

Applicants disagree. The novel aspect of this invention is that the selected alkylaryl polyether alcohol polymer, such as tyloxapol, alone and without any other pharmacologically active compounds, in disclosed dosages, achieves treatment and prevention

of snoring, sleep apnea, sudden infant death syndrome, etc. The prior art achieved treatment of sleep apnea with a composition comprising phospholipid alveolar lung surfactant compositions.

To again emphasize, this amendment eliminates any possibility that there could be any lung surfactant, phospholipid or any other pharmacologically active compound present in the composition unless disclosed in the specification on page 19, lines 9-14, as an additional therapeutic compounds selected from the group consisting of antibiotics, anti-inflammatories or analgesics.

Claims 1-36 and new claim 37 are not anticipated by the cited prior art. Rejection should be withdrawn and claims passed to issue. It is so respectfully requested.

SUMMARY

In summary, claims 1-36 are amended and new claim 37 is added to further distinguish these claims from cited references. All claims are deemed to be in condition for allowance. Notice of Allowance is respectfully requested.

Respectfully submitted,

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